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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| | | | |

| EXAMINER | |
|---|---|
| ART UNIT | PAPER NUMBER |
| | 5 |

**DATE MAILED:**

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

RL 6Y

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/419,927 | Sorensoen et al. |
| **Examiner** | **Art Unit** |
| Fozia Hamud | 1647 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) X Responsive to communication(s) filed on *Sep 27, 2000*.

2a) This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) X Claim(s) *1-3* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) X Claims *1-3* are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 4) Interview Summary (PTO-413) Paper No(s). _____ 5) Notice of Informal Patent Application (PTO-152) 6) Other: _____

## DETAILED ACTION

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a compound comprising a polysaccaride and extensin, classified in class 530, subclass 395.

II. Claim 2, drawn to a method for cytotxic enhancement of lymphocytes, classified in class 424, subclass 185.1.

III. Claim 3, drawn to a method for preparing a combination of extensin and a pectin or a polysacchride, class 514, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions II-III, are independent and distinct, each from the other, because the methods of Groups II-III are practiced for materially different purposes and each method requires a non-coextensive search because of different starting materials and goals.

Invention I is related to inventions II and III, because the method of invention II (i.e the method for cytotxic enhancement of lymphocytes), can use the compound of invention I. However, inventions I and II are distinct because the compound comprising a polysaccaride and extensin can be used in materially different methods, such as in diagnostic protocols, and likewise the method for cytotxic enhancement of lymphocytes can be practiced without the compound of invention I, such as by using the cytotoxic agent IL-12. Also the compound of invention I can be prepared in a materially different method other than the method of invention III, such as by using a nucleic acid

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Therefore, the following paragraph should be used by Applicants in a separate paper submitted, to invoke the procedure of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used for this application:

"The computer readable form in this application, 09/350,206, is identical with that filed in Application Number 09/042,780, filed March 17,1998, then in accordance with 37 CFR 1.821(e), please use the (first-filed, last-filed or only, whichever is applicable)computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing (included in the originally-filed specification of the instant application, or included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable)".

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Mondays, Thursdays and alternate Fridays from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
April 27, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J Saoud

ANSWER 2 OF 5 MEDLINE

AB PROBLEM: Human trophoblasts are tolerant to the maternal immune system, but susceptible to interleukin (IL)-2-activated **lymphocytes**. IL-12 is also a key **cytokine** in the induction of **cytotoxic** responses. We administered IL-12 to peripheral blood **lymphocytes** (PBLs) and to decidual **lymphocytes** (DLs) and studied resulting cytotoxicity against trophoblasts. METHOD OF STUDY: PBLs and DLs were stimulated with rIL-2 and/or rIL-12 for 48 hr in vitro. Cytotoxicity against the choriocarcinoma cell line JEG-3, JAR, and primary culture trophoblasts were examined by LDH release assay. The proliferative response was estimated by MTT assay. Expression of **cytotoxic factors** was studied by reverse transcriptase-polymerase chain reaction (RT-PCR). RESULTS: Whereas IL-12 alone produced a modest enhancement in cytotoxicity of PBLs and DLs, the combination of IL-2 and IL-12 was most effective in trophoblast cell lysis. IL-12 enhanced the mRNA expression of T-cell specific serine protease (TSP, granzyme B) and FasL in DLs, but the expression of perforin was unchanged. Expression of these **cytotoxic factors** in PBLs was up-regulated by IL-12. CONCLUSION: Our findings indicate critical roles of IL-12 in the activation of maternal **lymphocytes**, which could possibly result in pregnancy failure syndromes.